Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12860

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MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page ___ of ___

Form Approved OMB No 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence #

A. Patient information

1 Patient identifier [redacted] In confidence

2 Age at time of event: 29 or Date of birth:

3. Sex ☐ female ☒ male

4 Weight ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

☐ death ___ (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☑ other - addiction - psychological changes

3 Date of event (mo/day/yr) early 1997

4 Date of this report (mo/day/yr) 4/20/98

5 Describe event or problem

Consumer's mother called to report severe change in son's disposition/behavior since he started taking ephedra product beginning ≈ 11/96. Product is being distributed @ local gym where son exercises 4-6 times/week.

Behavioral changes include:
- leaving his wife who is 8 months pregnant
- drinking excessive amounts of EtOH (prior to ephedra use son did not drink EtOH at all)
- performance problems at his job
- stopped attending his church where he was previously a faithful member
- excessive weight loss (was not overweight)

Wife, and parents have confronted Consumer about these problems, but he insists that he is "fine" and that there is nothing wrong with the ephedra product.

Mom will attempt to gather more details about product/product use etc.

6 Relevant tests/laboratory data, including dates

4 RELEVANT TEST/LABS - Ø

7. Other relevant history, including preexisting medical conditions (e g, allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Ø - hospitalizations
Ø - EtOH } * prior to initiation of ephedra
Ø - ETOH } product use

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)

#1 ephedra containing product (2 scoops [redacted] of product contain 334 mg. ephedra)

2. Dose, frequency & route used

#1 1 scoop per dose - suspect taking it 4-6 times/week - unclear if taking according to label

3 Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 ≈ 12/96 - present

4. Diagnosis for use (indication)

#1 ergogenics/body building [redacted]

5 Event abated after use stopped or dose reduced

#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☒ doesn't apply

6 Lot # (if known)

#1
#2

7 Exp. date (if known)

#1
#2

8 Event reappeared after reintroduction

#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only)

10 Concomitant medical products and therapy dates (exclude treatment of event)

none known

D. Suspect medical device

1. Brand name

2 Type of device

3 Manufacturer name & address

4 Operator of device
☐ health professional
☐ lay user/patient
☐ other

5 Expiration date (mo/day/yr)

6
model #
catalog #
serial #
lot #
other #

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

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Report taken by GINN/CRRS

E. Reporter (see confidentiality section on back)

1 Name, address & phone #

[redacted]

2 Health professional? ☐ yes ☐ no

3 Occupation

4 Also reported to
☐ manufacturer
☐ user facility
☐ distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Notes on Telephone Conversation
Clinical Research and Review Staff

Date	4/20/1998	Phone No.	[redacted]
Name	[redacted]	Fax No.	
Affliation	(Consumer - forwarded to CRRS by [redacted]		
Address	[redacted]		
FDA Representatives			
Question/Subject	Wanted information on ephedra; he son is taking an ephedra product & is displaying severe behavioral changes.		

Discussion
CALLED TO FOLLOW-UP ON CONSUMER'S CORRESPONDENCE WITH FDA. MEDWATCH WAS COMPLETED BASED ON INFORMATION OBTAINED DURING THIS TELEPHONE CONVERSATION. MEDWATCH WILL BE SUBMITTED FOR ENTRY INTO AEMS DATABASE.

Follow up	ø

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Signed: Lisa R. Glenn Date: 4/22/98